REMARKS

Claims 1-9 are pending in the present application. Claim 1 has been amended to more clearly define the step of injecting a light-transmissive fluid into the lumen of the distal-end sleeve, and to recite that the light-diffusing tip, the light-transmissive fluid, and the distal sleeve scatter the light. Furthermore, claim 6 has been similarly amended. Also, the specification and claims 1 and 6 have also been amended to correct several typographical errors. It is submitted that these amendments are fully supported by the specification and do not introduce any new matter.

I. Rejections Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 6, 8, and 9 under 35 U.S.C. § 102(b), (hereinafter "Section 102(b)"), as being anticipated by United States Patent No. 5,700,243 to Narciso, Jr. (hereinafter "Narciso"). Applicants respectfully traverse this rejection.

Narciso discloses a balloon-type catheter with an integral fiber-optic assembly and a perfusion channel to allow fluid to flow around the inflated balloon during photo-irradiation. The catheter comprises multiple lumens, with at least one of them being an inflation passage for conducting inflation fluid to a balloon which coaxially surrounds the sheath near the distal end of the catheter. (Narciso, column 2, lines 27-35).

In contrast, the present invention relates to a catheter apparatus for use in photoatherolytic therapy. As seen in claim 6, the present invention comprises a catheter having a flexible, non-inflatable, translucent distal end sleeve. It is clear that Narciso does not disclose this claim recitation, as all of the embodiments of the device disclosed in Narciso utilize an inflatable balloon surrounding the sheath near the distal end of the catheter. Therefore, because Narciso does not disclose each and every element of the claimed invention, Narciso does not anticipate claim 6 of the present application or claims 8 and 9, both of which depend on claim 6.

The Examiner has also rejected claims 6, 8, and 9 under Section 102(b) as being anticipated by United States Patent No. 5,445,608 to Chen et al. (hereinafter "Chen"). Applicants respectfully traverse this rejection.

Claim 6 of the present application recites a proximal-end catheter port through which a light-transmissive fluid can be injected through the catheter into the lumen of the distal-end sleeve, and that a light beam transmitted through the fiber-optic bundle is scattered by the light-transmissive fluid injected into the lumen of the distal-end sleeve. None of the embodiments of Chen disclose this element of claim 6. Therefore, because Chen does teach each and every element of the claimed invention, Chen does not anticipate claim 6 or claims 8 and 9, both of which depend on claim 6.

Since Narciso and Chen both fail to disclose each and every element of claim 6, applicants respectfully request that the rejection be withdrawn. Furthermore, as claims 8 and 9 depend from claim 6, these claims are also not anticipated by Narciso or Chen.

Therefore, applicants also respectfully request that the rejection to claims 8 and 9 be withdrawn.

II. Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-5 under 35 U.S.C. § 103(a) (hereinafter "Section 103(a)") as being unpatentable over United States Patent No. Re. 34,544 to Spears (hereinafter "Spears") in combination with Chen. Applicants respectfully traverse this rejection.

Spears discloses a method of treating atherosclerosis by utilizing a balloon-type catheter to treat plaques. The device in Spears comprises a catheter with a hollow glass fiber 24 attached to the distal end of the catheter 12. The glass fiber is filled with a liquid 22. The lumen 12 of the catheter is in fluid connection with the balloon 14 at the distal end of the catheter 12 but not with the glass fiber 24 or the glass fiber's lumen. (Spears, column 2, line 34-63).

Spears fails to disclose the steps recited in amended claim 1 of injecting a light-transmissive fluid through the catheter into the lumen of the distal-end sleeve, and then having a light beam diffused by the fluid in the lumen of the distal-end sleeve. Because the lumen of the glass fiber in Spear's device is not in fluid connection with the catheter lumen, a light-transmissive fluid injected through the catheter cannot enter the lumen of the glass fiber located at the distal end of Spear's device. Furthermore, Chen does not remedy the deficiency in Spears. In particular, as discussed above, Chen also fails to disclose a step ofinjecting the light-transmissive fluid through the catheter into the lumen of the distal end sleeve as recited in the claims. Therefore, both Spears and Chen, either singly or in combination, fail to disclose each and every element of amended claim 1, and applicants respectfully request that the rejection to claim 1 be withdrawn. As claims 2-5 depend from independent claim 1, applicants respectfully request that the rejection to claims 2-5 also be withdrawn.

Claims 6 and 7 have been rejected under Section 103(a) as being unpatentable over Chen or Narciso. As noted above, Chen fails to disclose or suggest injecting a light-transmissive fluid into the lumen of the distal-end sleeve and scattering the light by the fluid in the lumen. Therefore, Chen fails to disclose or suggest all of the elements of claim 6. As claim 7 depends from independent claim 6, claim 7 is also patentable over Chen. Applicants therefore respectfully request that the rejection to claims 6 and 7 be withdrawn.

Moreover, as discussed earlier, Narcisco fails to disclose or suggest a non-inflatable distal end sleeve as recited in claims 6 and 7. Instead, Narcisco discloses a balloon-type catheter. Thus, Narcisco does not render claims 6 and 7 as obvious.

Favorable consideration of Applicants' claimed invention is respectfully solicited. It is respectfully believed that the present claims are in condition for allowance, early notice of which would be appreciated. Submitted along with this response is a petition for a two-month extension under C.F.R. 1.136(a). The fee believed due for this petition is $205.00 (small entity). Please charge the required amount due to Pennie & Edmonds LLP Account No. 16-1150.

Respectfully submitted,

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Date: March 20, 2003

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EXHIBIT A

Marked-up version of the specification

Page 2, third paragraph

After thus positioning the catheter's distal-end sleeve within the target region, the guidewire is removed, and replaced with a fiber-optic bundle having a light-diffusing tip, until the tip is positioned adjacent the catheter juncture. After injecting a light-transmissive fluid, such as a transparent or translucent aqueous solution, through the catheter into the catheter's distal-end sleeve, the target region is irradiated by passing a laser light beam through the fiber optic bundle. The beam is distributed along the catheter's distal-end sleeve, for transmission through the sleeve, by light scattering produced by **(i)** the light-diffusing tip, (ii) the light-transmissive fluid in the catheter's distal-end sleeve, and/or (iii) the distal sleeve itself. The scattered light is effective to photoactivate a photoatherolytic compund contained in the target region. Irradiation is typically carried out for 10-20 minutes.

Page 3, third paragraph

Also included in the apparatus are (i) a fiber-optic having a light-diffusing tip, the bundle being adapted to be introduced through the catheter lumen, with the catheter's distal-end sleeve placed within the target site, (ii) [an] a proximal-end catheter port through which a light-transmissive fluid can be injected thought the catheter into the catheter's distal-end sleeve, and (iii) a proximal-end optical connector through which the fiber-optic bundle can be connected to a light source, such as a laser, for irradiating the atherosclerotic vessel region by passing, for example, a laser light beam, through the fiber-optic bundle. In operation, a light beam, again for example, a laser light beam, is distributed along the catheter's distal-end sleeve, for transmission through the sleeve, by light scattering produced by **(i)** the light-diffusing tip, **(ii) the** light-transmissive fluid injected into the catheter's distal-end sleeve and/or (iii) the distal sleeve itself.

Page 5, first paragraph:

Figs. 1 and 2 show a distal-end portion of the apparatus, indicated at 12, showing the distal-end portion of a catheter jacket 14, a distal-end diffuser 16, and a juncture 18 between the two. The distal-end diffuser may be transparent or translucent, providing either a transparent light sleeve or a light-scattering sleeve. This distal section of the catheter is made from an optically transparent, heat stable, flexible material, such as **a** crosslinked polymer, for example polyethylene or [poly(tetrafluoro ethylene)] **polytetrafluroroethylene** (PTFE). The flexibility allows the catheter to track easily over the wire, [and] the transparentcy allows light to escape through the wall, **and** heat stability prevents heat deformation from the light energy. Light scattering particles may be added to the sleeve material.

Page 6, second paragraph:

Figs. 3A-3D show the positioning of a distal end portion of the apparatus within a chamber of a heart 26, for accessing a vascular target region of the heart in need of phototherapy. Initially, although not shown, the patient is administered a photosensitizing compound, typically by systemic administration, and the compound is allowed to accumulate at the target site, according to known phototherapy principles. [A broader view of a patient orExemplary] **Exemplary** photosensitizing compounds are those used in phototherapy, [such as compound may be one currently used in photodynamic therapy,] such as a phycocyanin, a phthalocynanine, pheophorbide derivative PH-1126, mono-L-aspartyl chlorin e6 (NPe6), hematoporhyrin derivative (HpD), benzoporphyrin derivative (BPD), Photofrin and Photofrin 2, protoporphyrin IX, and dihematoporphyrin-ester and -ether (DHE).

EXHIBIT B

Marked-up Version of Amended Claims

1. (Amended) A method of treating an atherosclerotic target region of a coronary vessel in a patient, comprising

delivering to the patient[,] a photoatherolytic compound[,] to cause accumulation of the compound in the target region,

accessing the target region intraluminally with a guidewire,

advancing over the guidewire[,] a catheter having (i) a proximal main-body sleeve, (ii) a flexible, non-inflatable, translucent distal-end sleeve joined to the main-body sleeve at a catheter juncture, and (iii) an inner lumen extending through the two sleeves, said advancing being effective to position to the catheter's distal-sleeve within the target region,

removing the guidewire from the catheter,

introducing through the catheter[,] a fiber-optic bundle having a light-diffusing tip, until said tip is positioned adjacent the catheter juncture,

injecting a light-transmissive fluid through the catheter into the [catheter's] **lumen of the** distal-end sleeve, and

irradiating the atherosclerotic vessel region by passing a laser light beam through the fiber optic bundle,

wherein said beam is distributed along the catheter's distal-end sleeve, for transmission through the sleeve, by light scattering produced by [at least one of said] **(i) the** light-diffusing tip, (ii) the light-transmissive fluid in the [catheter's] **lumen of the** distal-end sleeve and (iii) the distal sleeve [itself], and the scattered light transmitted through the sleeve is effective to photoactivate the photoatherolytic compound contained in the target region.

6. (Amended) Apparatus for use in treating an atherosclerotic target region of a coronary vessel in a patient, comprising

a guidewire for accessing the target region intraluminally,

a catheter having (i) a proximal main-body sleeve, (ii) a flexible, non-inflatable, translucent distal-end sleeve joined to the main-body sleeve at a catheter juncture, and (iii) an inner lumen extending through the two sleeves, through which lumen the catheter can be advanced over the guidewire, with such positioned in the target region, to place the catheter's distal-end sleeve within the target region,

a fiber-optic bundle having a light-diffusing tip, said bundle being adapted to be introduced through the catheter lumen, with the catheter's distal-end sleeve placed within the target site,

a proximal-end catheter port through which a light-transmissive fluid can be injected through the catheter into the [catheter's] **lumen of the** distal-end sleeve, and

a proximal-end optical connector through which the fiber-optic bundle can be connected to a laser source, for irradiating the atherosclerotic vessel region by passing a laser light beam through the fiber optic bundle,

such that the laser beam is distributed along the catheter's distal-end sleeve, for transmission through the sleeve, by light scattering produced by [at least one of] (i) [said] **the** light-diffusing tip, (ii) **the** light-transmissive fluid injected into the [catheter's] **lumen of the** distal-end sleeve, and (iii) the distal sleeve [itself], and where the scattered light transmitted through the sleeve is effective to photoactivate the photoatherolytic compound contained in the vessel region.

EXHIBIT C
List of Currently Pending Claims

1. (Amended) A method of treating an atherosclerotic target region of a coronary vessel in a patient, comprising

delivering to the patient a photoatherolytic compound to cause accumulation of the compound in the target region,

accessing the target region intraluminally with a guidewire,

advancing over the guidewire a catheter having (i) a proximal main-body sleeve, (ii) a flexible, non-inflatable, translucent distal-end sleeve joined to the main-body sleeve at a catheter juncture, and (iii) an inner lumen extending through the two sleeves, said advancing being effective to position to the catheter's distal-sleeve within the target region,

removing the guidewire from the catheter,

introducing through the catheter a fiber-optic bundle having a light-diffusing tip, until said tip is positioned adjacent the catheter juncture,

injecting a light-transmissive fluid through the catheter into the catheter's distal-end sleeve, and

irradiating the atherosclerotic vessel region by passing a laser light beam through the fiber optic bundle,

wherein said beam is distributed along the catheter's distal-end sleeve, for transmission through the sleeve, by light scattering produced by (i) the light-diffusing tip, (ii) the light-transmissive fluid in the catheter's distal-end sleeve and (iii) the distal sleeve, and the scattered light transmitted through the sleeve is effective to photoactivate the photoatherolytic compound contained in the target region.

2. The method of claim 1, wherein the photoatherolytic compound is selected from the group consisting of a phycocyanin, a phthalocynanine, pheophorbide derivative PH-1126, mono-L-aspartyl chlorin e6 (NPe6), hematoporhyrin derivative (HpD), benzoporphyrin derivative (BPD), Photofrin and Photofrin 2, protoporphyrin IX, and dihematoporphyrin-ester and -ether (DHE).

3. The method of claim 1, wherein said injecting includes forcing a transparent or translucent aqueous solution through the catheter lumen.

4. The method of claim 1, wherein said irradiating is carried out for a total of between about 10-20 minutes.

5. The method of claim 4, wherein the catheter has a catheter wall port distal to said juncture, said port is positioned downstream of the target region in the coronary vessel, when the catheter is fully advanced, and said method further includes, at one or more

intervals, during said irradiating step, retracting the catheter to position said port upstream the target, and thereby allow blood in said vessel to flow into and through said distal end region, to promote blood flow through the target region of the vessel at intervals during the treatment procedure.

6. Apparatus for use in treating an atherosclerotic target region of a coronary vessel in a patient, comprising

a guidewire for accessing the target region intraluminally,

a catheter having (i) a proximal main-body sleeve, (ii) a flexible, non-inflatable, translucent distal-end sleeve joined to the main-body sleeve at a catheter juncture, and (iii) an inner lumen extending through the two sleeves, through which lumen the catheter can be advanced over the guidewire, with such positioned in the target region, to place the catheter's distal-end sleeve within the target region,

a fiber-optic bundle having a light-diffusing tip, said bundle being adapted to be introduced through the catheter lumen, with the catheter's distal-end sleeve placed within the target site,

a proximal-end catheter port through which a light-transmissive fluid can be injected through the catheter into the catheter's distal-end sleeve, and

a proximal-end optical connector through which the fiber-optic bundle can be connected to a laser source, for irradiating the atherosclerotic vessel region by passing a laser light beam through the fiber optic bundle,

such that the laser beam is distributed along the catheter's distal-end sleeve, for transmission through the sleeve, by light scattering produced by (i) the light-diffusing tip, (ii) the light-transmissive fluid injected into the catheter's distal-end sleeve and (iii) the distal sleeve, and where the scattered light transmitted through the sleeve is effective to photoactivate the photoatherolytic compound contained in the vessel region.

7. The apparatus of claim 6, wherein said catheter has an inner-lumen diameter of between about .45 and .6 mm.

8. The apparatus of claim 6, wherein the optic fiber bundle is formed of a plurality of light fibers encased in an outer sleeve for relative axial fiber sliding movement, to enhance the flexibility of the fiber bundle.

9. The apparatus of claim 6, wherein said catheter has a wall port downstream of said juncture, and located to allow blood in the patient's vessel to flow into and through said distal end sleeve, with the catheter distal-end sleeve placed in the target region, and withdrawn to place the port just upstream of the target region.